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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,159	09/27/2001	Rolf Dieter Schraft	SPM-328-B	3931

7590 08/28/2003

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EXAMINER	
BAXTER, JESSICA R	

ART UNIT	PAPER NUMBER
3731	9

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PR

Office Action Summary	Application No.	Applicant(s)	
	09/965,159	SCHRAFT ET AL.	
	Examiner	Art Unit	
	Jessica R Baxter	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 Feb 2002, 31 July 2002 07 Oct 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 May 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The transiation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "12" has been used to designate both a guide track and a spiral needle. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. (See Page 6 lines 9-12)

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "15" has been used to designate both a guide track and an opening. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. (See page 6 lines 25-31)

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the carrier element must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The carrier element is inherently already in the drawings, however it is not pointed out in the drawings.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claims 1, 2, 4, 12 and 28, the phrase "and/or" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

7. Claim 2 recites the limitation "the region" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 8 recites the limitation "the roller" in line 1. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 9 recites the limitations "the region" in lines 1-2 and "the second surface" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claim 9 recites the term "outwith" in line 2. This term is not understood.

10. Claim 10 recites the limitation "the second surface" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 12 recites the limitation "further suction openings" in line 2. There is insufficient antecedent basis for this limitation in the claim since there are no other suction openings claims 1 or 12.

12. Claim 19 recites the limitation "the probe knife" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is not clear what is meant by the phrase "extend in introduced into the artery" in line 3.

13. Claim 21 recites the limitation "the second surface" in line 2. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 22 is an incomplete sentence.

15. Claim 27 recites the limitation "the adapter element" in line 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 30 recites the limitation "the thread ends" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

18. Claims 1-6, 9-18, 21-26 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,947,983 to Solar et al.

Regarding claim 1, Solar discloses a device for connecting hollow organs and/or sealing wall defects in hollow organs, having a base mounting (tube 110) which has at least one recess on a first surface (window 111); at least one guidetrack (lumen of tube 110)for at least one spiral needle in which a spiral needle (needle 140) is movable forwards in a rotatable fashion; and the guidetrack for the spiral needle being disposed at least partially along the edge of the recess in such a manner that the track of the spiral needle during a revolution extends partially in the base mounting and partially in the recess(FIG. 2D).

Regarding claim 2, Solar discloses that the guidetrack in the region at a distance from the recess and/or in the region along the edge of the recess has the configuration of a spiral or of circular segments of a spiral (groove 122).

Regarding claim 3, Solar discloses that the guidetrack in the region along the edge of the recess has the configuration of circular segments of a spiral, the respective ends of which form openings in the base mounting along the edge of the recess (helical groove 122).

Regarding claim 4, Solar discloses that the guidetrack in the region at a distance from the recess and/or in the region along the recess has the configuration of a spiral or of circular segments of a spiral and has an internal diameter which is greater than or equal to the diameter of a spiral

Needle (FIG. 2D groove 122).

Regarding claim 5, Solar discloses that the guidetrack in the region at a distance from the recess is configured as a boring with an internal diameter which is greater than or equal to the external diameter of the spiral formed by the spiral needle (FIG. 2D).

Regarding claim 6, Solar discloses at least in portions along the recess on the surface of the base mounting there are disposed suction openings for drawing in and fixing the edges of an opening of a hollow organ (Column 3 lines 36-49).

Regarding claim 9, Solar discloses that the guidetrack in the region outwith the recess along its direction of passage is opened towards the second surface of the base mounting which is situated opposite the first surface.

Regarding claim 10, Solar discloses that between the second surface and the guidetrack, a slot is disposed along the guidetrack (window 121).

Regarding claim 11, Solar discloses that at least along the recess, the surface of the base mounting has a recess for receiving a hollow organ.

Regarding claim 12, Solar discloses that on the first surface, further suction openings are disposed for drawing in tissue and/or a hollow organ (Column 3 lines 36-49).

Regarding claim 13, Solar discloses that the base mounting has a carrier element on its side orientated towards the first surface, which carrier element is mounted rotatably on the base mounting (tube 120).

Regarding claim 14, Solar discloses that the carrier element has suction openings for drawing in a tissue or a hollow organ (window 121 and Column 3 lines 36-49).

Regarding claim 15, Solar discloses that the carrier element has an annular configuration (FIG. 2D).

Regarding claim 16, Solar discloses that the carrier element extends along the external edge of the first surface (FIG. 2D).

Regarding claim 17, Solar discloses that the guidetrack is disposed along the recess in such a manner that the spiral needle can be guided at least partially between two edges of the recess which are situated opposite each other (FIG. 2D).

Regarding claim 18, Solar discloses that the guidetrack is disposed in portions along two edges of the recess which are situated opposite each other in such a manner that the portions of the guidetrack which are disposed along the edges of the recess which are situated opposite each other form segments of a single spiral (FIG. 2D groove 122).

Regarding claim 21, Solar discloses that the recess extends from the first to the second surface (FIG. 2D).

Regarding claim 22, Solar discloses that an adapter element which is configured so as to be engagable at least partially in a form fitting manner from the direction of the second surface into the recess (tube 120).

Regarding claim 23, Solar discloses that the adapter element has a boring for receiving a hollow organ portion, which boring extends from the side orientated towards the base mounting to the side orientated away from the base mounting (windows 111, 121).

Regarding claim 24, Solar discloses that the longitudinal axis of the boring extends at a predetermined angle relative to the first surface (FIG 2D).

Regarding claim 25, Solar discloses that the walls of the boring have suction openings for drawing in and fixing a hollow organ portion or its edge (Column 3 lines 36-49).

Regarding claim 26, Solar discloses that the walls of the boring have at least one guidetrack which completes that at least one guidetrack of the base mounting to form a common guidetrack for a spiral needle (groove 122).

Regarding claim 28, Solar discloses the method for connecting hollow organs and/or for sealing wall defects in hollow organs, characterized in that by using a device according to claim 1,

comprising the step of guiding at least one spiral needle in a rotating manner through the adjacent edges of the same or of two different hollow organ openings (Column 3 line 36-Column 4 line 14).

Regarding claim 29, Solar discloses the step of pulling a thread through the edge of the opening of the hollow organ with each spiral needle (FIG. 2E suture 145).

Regarding claim 30, Solar discloses the steps of removing the spiral needle and connecting the thread ends to each other (Column 4 lines 43-54).

Regarding claim 31, Solar discloses the step of tying the thread ends to each other (Column 4 lines 43-54).

19. Claims 1-5, 7-11, 13, 15-22 and 27-31 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,015,416 to Stefanchik et al.

Regarding claim 1, Stefanchik discloses a device for connecting hollow organs and/or sealing wall defects in hollow organs, having a base mounting (implement 20) which has at least one recess on a first surface (FIG. 10); at least one guidetrack for at least one spiral needle in which a spiral needle is movable forwards in a rotatable fashion (FIG. 13); and the guidetrack for the spiral needle being disposed at least partially along the edge of the recess in such a manner that the track of the spiral needle during a revolution extends partially in the base mounting and partially in the recess (FIG. 14).

Regarding claim 2, Stefanchik discloses that the guidetrack in the region at a distance from the recess and/or in the region along the edge of the recess has the configuration of a spiral or of circular segments of a spiral (fig. 14 guides 77 and 78).

Regarding claim 3, Stefanchik discloses that the guidetrack in the region along the edge of the recess has the configuration of circular segments of a spiral, the respective ends of which form openings in the base mounting along the edge of the recess (FIG. 14).

Regarding claim 4, Stefanchik discloses that the guidetrack in the region at a distance from the recess and/or in the region along the recess has the configuration of a spiral or of circular segments of a spiral and has an internal diameter which is greater than or equal to the diameter of a spiral needle (FIG. 14).

Regarding claim 5, Stefanchik discloses that the guidetrack in the region at a distance from the recess is configured as a boring with an internal diameter, which is greater than or equal to the external diameter of the spiral formed by the spiral needle (FIG. 14 and 17).

Regarding claim 7, Stefanchik discloses that along the guidetrack there is disposed at least one roller (rollers 70 and 71), the axis of rotation of which is essentially parallel to the direction of passage of the guidetrack.

Regarding claim 8, Stefanchik discloses that the roller is connected to a drive in a non-positive manner for rotation of the roller (drive 106 and 108).

Regarding claim 9, Stefanchik discloses that the guidetrack in the region outwith the recess along its direction of passage is opened towards the second surface of the base mounting which is situated opposite the first surface (FIG. 17).

Regarding claim 10, Stefanchik discloses that the second surface and the guidetrack, a slot is disposed along the guidetrack (FIG. 17 a slot is on both sides of the base mounting).

Regarding claim 11, Stefanchik discloses that at least along the recess, the surface of the base mounting has a recess for receiving a hollow organ (in between clamp 50).

Regarding claim 13, Stefanchik discloses that the base mounting has a carrier element on its side orientated towards the first surface, which carrier element is mounted rotatably on the base mounting (clip 80, prong 84).

Regarding claim 15, Stefanchik discloses that the carrier element has an annular configuration (FIG. 24).

Regarding claim 16, Stefanchik discloses that the the carrier element extends along the external edge of the first surface (FIG. 10 and 11).

Regarding claim 17, Stefanchik discloses that the guidetrack is disposed along the recess in such a manner that the spiral needle can be guided at least partially between two edges of the recess which are situated opposite each other (FIG. 14 and 17).

Regarding claim 18, Stefanchik discloses that the guidetrack is disposed in portions along two edges of the recess which are situated opposite each other in such a manner that the portions of the guidetrack which are disposed along the edges of the recess which are situated opposite each other form segments of a single spiral (FIG. 13 and 14).

Regarding claim 19, Stefanchik discloses that the at least two guidetracks (guide 77 and 78) are disposed in the base mounting and, situated opposite each other (FIG. 14), extend in introduced into the artery to be sutured and the probe knife has a probe at its tip which is flexible and in the central part of the probe knife there is located a blade (cutting edge 116 and 118).

Regarding claim 20, Stefanchik discloses that the two guidetracks intersect at least one of the beginning and at the end of their course along the recess, intertwine in each other or extend directly adjacent to each other (FIG. 14).

Regarding claim 21, Stefanchik discloses that the recess extends from the first to the second surface (FIG. 15 slot in between housings 64).

Regarding claim 22, Stefanchik discloses that the adapter element (FIG. 17) which is configured so as to be engagable at least partially in a form fitting manner from the direction of the second surface into the recess (Clip 80 prongs 82 and 84).

Regarding claim 27, Stefanchik discloses that at least one of the base mounting and the adapter element can be divided into at least two parts along the recess. The device is made of different parts, therefore it can be divided along the recess.

Regarding claim 28, Stefanchik discloses the method for connecting hollow organs and/or for sealing wall defects in hollow organs, characterized in that by using a device according to claim 1, comprising the step of guiding at least one spiral needle in a rotating manner through the adjacent edges of the same or of two different hollow organ openings (Column 9 lines 26-65).

Regarding claim 29, Stefanchik discloses the step on pulling a thread through the edge of the opening of the hollow organ with each spiral needle (stitches 164).

Regarding claim 30, Stefanchik discloses the steps of removing the spiral needle and connecting the thread ends to each other (Column 10 lines 13-20).

Regarding claim 31, Stefanchik discloses the step of tying the thread ends to each other (Column 10 lines 13-20).

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited to further show the state of the art with respect to helical needle suturing devices:

U.S. Patent No. 5,364,408 to Gordon

U.S. Patent No. 5,470,338 to Whitfield et al.

U.S. Patent No. 5,665,109 to Yoon

U.S. Patent No. 5,820,631 to Nobles

U.S. Patent No. 6,315,784 to Djurovic

U.S. Patent No. 6,514,263 to Stefanchik et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

jrb
August 25, 2003

Julian W. Woo
Julian W. Woo
Primary Examiner